m375n.pdf

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 7, 1997

Our Reference: 2937960

Keith W. Hensley, President
Formulation Technology, Inc.
571 Armstrong Way
Oakdale, CA 95361

WARNING LETTER

Dear Mr. Hensley:

The Food and Drug Administration (FDA) received a complaint regarding injuries sustained by a young woman who experienced an abnormal heart rate with complete heart block, a potentially life-threatening condition. The consumer's symptoms were consistent with an overdose of digitalis-like cardiac glycosides. The young woman experienced this condition after ingesting a regimen of dietary supplements. FDA's investigation determined that the problem was due to the ingredient plantain found in the dietary supplement "Chomper."

Our investigation found that your firm received contaminated plantain powder from one or more lots and used this plant material in the manufacture of Chomper tablets and bulk powder for [redacted].

The Chomper tablets and bulk Chomper powder that you produced with the contaminated plantain are adulterated under the provisions of the Federal Food, Drug and Cosmetic Act (the Act) as follows:

- within the meaning of section 402(a)(1) in that they contain an added poisonous or deleterious substance, namely lanatosides (cardiac glycosides), which may render them injurious to health;

- within the meaning of section 402(f)(1)(A) of the Act in that they are dietary supplements, which contain lanatosides, e.g. cardiac glycosides, that present a significant or unreasonable risk of illness under conditions of use recommended or suggested in the product's labeling.

FDA collected samples of plantain, identified as lot numbers [redacted] which were either used or destined for use in the manufacture of Chomper products for [redacted]. Analyses of these samples showed that the plant material identified as "plantain," contained lanatosides (cardiac glycosides). The presence of lanatosides support that the plant material contains *Digitalis* glycosides. *Digitalis lanata* has been reported to contain these lanatosides. Plantain has not been reported to contain any cardiac glycosides.

FDA also conducted an analysis of a sample of plantain to determine whether the material identified as plantain actually contained plantain. The analysis found that the characteristic trichomes for plantain were low in concentration in the sample when compared to reference specimens. These analyses indicate that the plantain was contaminated with *Digitalis*.

As a manufacturer, you are responsible for ensuring that ingredients which you use in manufacturing dietary supplements are safe for human consumption. We note that [redacted] voluntarily recalled the adulterated Chomper products that you manufactured for [redacted] and distributed to [redacted] for labeling and bottling. However, we are concerned that this type of situation does not occur again.

We request that you notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to preclude this violation from occurring in the future. If you continue to manufacture dietary supplements that are adulterated as stated above, FDA may consider initiating regulatory action, such as seizure or injunction.

Your reply should be addressed to:

Sam M. Ali
Recall and Emergency Coordinator
U.S. Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502

Telephone (510) 337-6869
FAX (510) 337-6705

Sincerely,

Charles D. Moss

Charlie D. Moss
Acting District Director
San Francisco District